Article - Health - General

[Previous][Next]

§21–2C–01.

(a) In this subtitle the following words have the meanings indicated.

(b) "Biologic" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 C.F.R. § 447.502.

(c) "Biosimilar" means a drug that is produced or distributed in accordance with a biologics license application approved under 42 U.S.C. § 262(k)(3).

(d) "Board" means the Prescription Drug Affordability Board.

(e) (1) "Brand name drug" means a drug that is produced or distributed in accordance with an original new drug application approved under 21 U.S.C. § 355(c).

(2) "Brand name drug" does not include an authorized generic as defined by 42 C.F.R. § 447.502.

(f) "Generic drug" means:

(1) A retail drug that is marketed or distributed in accordance with an abbreviated new drug application, approved under 21 U.S.C. § 355(j);

(2) An authorized generic as defined by 42 C.F.R. § 447.502; or

(3) A drug that entered the market before 1962 that was not originally marketed under a new drug application.

(g) "Manufacturer" means an entity that:

(1) (i) Engages in the manufacture of a prescription drug product; or

(ii) Enters into a lease with another manufacturer to market and distribute a prescription drug product under the entity's own name; and

(2) Sets or changes the wholesale acquisition cost of the prescription drug product it manufactures or markets.

(h) "Prescription drug product" means a brand name drug, a generic drug, a biologic, or a biosimilar.

(i) "Stakeholder Council" means the Prescription Drug Affordability Stakeholder Council.

[Previous][Next]